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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	3000	8326

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/981,665

Applicant(s)

CIPKOWSKI, STAN

Examiner

James L. Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006 and 29 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 24 August and 29 August 2006 have been entered. Claims 16-19 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to the claims as now amended, the specification, as originally filed, does not provide support for a sample receiving portion on the front surface of the test strip so that liquid sample flows through the sample receiving opening and directly contacts the front surface of the

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sample receiving portion. Applicant provides no guidance in the specification for certain particulars of the test strip structure. There is no disclosure in the instant specification regarding whether the instant test strip does or does not include an absorbent pad at the sample receiving portion. Applicant, in this regard, merely discloses that specimen is able to contact the “absorbent or sample portions” of the test strips through the sample openings (see e.g. page 12). Moreover, there is no specific teaching in the instant specification regarding whether the instant test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al. (WO 88/08534). Such sandwiching would affect the size and shape of the “sample portion” and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the “sample portion” may only be the cut end. Although one of skill in the art might realize from reading the disclosure that absorbent or sample receiving portions on the front surface of the test strips are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Applicant's arguments filed 24 August 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, as set forth above, there would seem no support for direct contact of sample with the front surface of a

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sample receiving portion on the front surface of the test strip as is now claimed. As set forth, the disclosure noted by applicant that specimen is able to contact the “absorbent or sample portions” of the test strips through the sample openings does not indicate that the contact is limited only to direct contact with the test strip and not an “absorbent portion” or that the absorbent or sample portions are on the front surface of the test strip or that specimen contacts the front surface of the absorbent or sample portions. Description of such structural/functional elements of the test strips are entirely lacking in the specification as filed.

Claims 16 and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652) for reasons of record.

Claims 16-19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652), and further in view of Boger et al. (US 4,518,565) for reasons of record.

Applicant's arguments filed 24 August 2006 and the declaration of Keith Palmer under 37 CFR 1.132, filed 29 August 2006, have been fully considered but they are not deemed to be persuasive.

Applicant urges that the immunoassays of the instant invention comprise an improvement to obtain a test in a quick, simple and effective manner. This is not found persuasive because there is nothing to support applicant's asserted “improvement.” Applicant clearly admits that the test strips for performance of the immunoassay were commercially available (see pages 8-9).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Notwithstanding applicant's assertions to the contrary, May et al. specifically teach that the porous carrier can directly communicate with the casing exterior. There is nothing to support applicant's assertions of function of the instant strips and carrier/casing/holder in a "far different" manner from that taught by the references because capillary action also moves the sample through the porous carriers of May et al. (see e.g. page 4) or Sun et al. (see e.g. col. 6), which can directly communicate with the casing exterior.

Applicant further argues other specifics of the particular device depicted in Fig. 11 of May et al. Notwithstanding applicant's assertions to the contrary, the presence of a transparent backing sheet in the observation apertures of this particular embodiment is of no moment to the rejection of record. Again, applicant's specification lacks any teaching of test strip structure and any teaching regarding whether the instant test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al. Applicant also urges that the porous receiving member and not the porous carrier directly contacts sample in the embodiment depicted in this Fig. This is not found persuasive for a number of reasons. Applicant's argument does not address the reasons set forth in the rejection of record regarding the obviousness and motivation for combinations of features. As set forth, May et al. specifically teach that the porous carrier can directly communicate with the casing exterior and that combinations of features of the specifically exemplified embodiments were contemplated. As set forth, May et al. or Boger et al. clearly teach apertures on the front of casings/holders registering with sample application portions of test strips therein.

Applicant's arguments regarding undisclosed features of the test strips were not found persuasive for the reasons set forth above under 35 USC 112 and incorporated herein. Further, as set forth, May et al. specifically exemplify casings having apertures in the front or end of the casing for sample application, and specifically teach that the dry porous carrier communicates directly, or indirectly via a porous receiving member, with the exterior of the casing such that sample can be applied to the porous carrier (see e.g. page 3, or claims) and that combinations of features of the specifically exemplified embodiments were contemplated. As set forth, applicant's specification is silent on the presence or absence of an absorbent pad at the "absorbent or sample portions" of the sample receiving portion of the test strip. Notwithstanding applicant's assertions to the contrary, either the porous carrier or the porous receiving member of May et al., which also may be present on the undisclosed structure of applicant's test strips, directly contacts the sample. For the reasons of record, one would have been motivated to provide a casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that such combinations were possible and that the sample receiving portion thereof was not sufficiently robust to protrude from a casing and one would have expected the combination to function as desired. Moreover, notwithstanding applicant's arguments to the contrary, there is nothing found in the disclosure of May et al. that excludes bathing an entire sample receiving portion of a dry porous carrier without a porous receiving member, as depicted in Fig. 1, when contacted with a sample in a casing such as that depicted in Figs. 5 or 6 or 11. The shape of the apertures and their placement on the end or front of the casing would seem obvious matters of design choice.

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Applicant urges that the declaration of Keith Palmer provides evidence of secondary considerations of nonobviousness because of the commercial success noted in the declaration of the RAPID DRUG SCREEN[®] test kit. This is not found persuasive because it is not clear that the commercial success of the kit comprising a test card and a specimen container with a slotted lid which accommodates the test card is due merely to the test card, as instantly claimed, and not to the combination as patented (see US 5,976,895).

Claims 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,372,515 B1 for reasons of record.

Applicant's prior offer to file a terminal disclaimer is again noted. The rejection is maintained until it is overcome by, in particular, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c).

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Grun

James L. Grun, Ph.D.

November 7, 2006

Long V. Le

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